

REMARKS

This Amendment is responsive to the Office Action dated September 5, 2008. Applicant has amended claims 20-23, 26, 28, 29, 35-38, 40, 43, 53, 55, 57, 59-61, 72 and 73, and canceled claims 19, 24, 25, 39, 41, 42, 54 and 56. Claims 1-18, 34, 46-52, and 63-71 were previously canceled. Claims 20-23, 26-33, 35-38, 40, 43-45, 53, 55, 57-62, 72 and 73 are pending.

Claim Rejection Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 19-33, 35-45, 53-62, 72 and 73 under 35 U.S.C. § 103(a) as being unpatentable over Hatlestad et al. (US 2005/0042589, herein referred to as “Hatlestad”) in view of Sazonov et al. (Institute of Physics Publishing, *Physiological Measurement* 25 (2004) 1292-1304, herein referred to as “Sazonov”). Applicant respectfully traverses the rejection to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant’s claims, and provide no teaching that would have suggested a rational reason for modification to arrive at the claimed invention.

The Examiner cited Hatlestad as teaching the requirements of independent claims 53, 72, and 73, including monitoring a plurality of physiological parameters based on signals output from sensors, determining a plurality of sleep metric values based on respective physiological parameters, and determining a value of an overall sleep metric by averaging the values of a plurality of sleep metrics. The Examiner acknowledged that Hatlestad does not disclose sleep metric values that indicate a non-binary probability of the sleep state of the patient. To overcome this admitted deficiency of Hatlestad, the Examiner suggested modifying the sleep evaluation device of Hatlestad to determine the probability of sleep in a subject, as taught by Sazonov.

Applicant submits that even if Hatlestad were modified in view of Sazonov the resulting combination would not disclose or suggest each and every element of independent claims 53, 72 and 73.

Hatlestad describes a sleep detection unit including two sensors.¹ A sleep detection sensor detects a first sleep-related condition. The first sleep-related condition is compared to a sleep threshold to detect sleep onset and termination. A threshold adjustment sensor detects a

¹ Hatlestad, paragraphs [0081] and [0082].

second sleep-related condition that is used to adjust the sleep threshold. The sleep threshold may be increased or decreased depending on the value of the second sleep-related condition. The sleep detection unit compares a value of the first sleep-related condition to the sleep threshold and makes a binary determination of whether the patient is asleep based on the comparison.

Sazonov describes using logistic regression and neural networks to create mathematical models that predict whether or not a subject is asleep based on a single physiological parameter. For example, according to Sazonov, sleep data may be fit to a logistic curve to create a mathematical model that generates a binary determination of “Sleep” or “Wake” based on an accelerometer signal. According to Sazonov, the model may determine a probability that the subject is asleep based on an accelerometer signal, and then determine that the subject is asleep if the probability that the subject is asleep is greater than 0.5.²

Neither Hatlestad nor Sazonov disclose or suggest determining a plurality of sleep quality metrics that each indicate a non-binary probability of the patient being asleep based on a respective physiological parameter, as required by Applicant’s amended independent claims. Additionally, neither Hatlestad nor Sazonov disclose or suggest mathematically combining a plurality of sleep metric values that each indicate a non-binary probability of the patient being asleep to determine an overall sleep metric value that indicates an overall non-binary probability of the patient being asleep, as required by Applicant’s amended independent claims. Sazonov describes determining a single probability value based on a signal from a single accelerometer sensor and making a binary determination of “Sleep” or “Wake” based on the single probability. Contrary to the Examiner’s assertions, Hatlestad does not disclose or suggest any sleep metric that indicates the probability of a patient being asleep, and also fails to disclose or suggest mathematically combining any “sleep metrics” used in the sleep detection process.

The Examiner cited paragraphs [0090]-[0103] of Hatlestad as describing a process of determining an overall sleep metric value by averaging values of a plurality of sleep metrics. However, the cited portion of Hatlestad discusses an embodiment of a binary sleep detection method that utilizes an activity sensor as the sleep detection sensor and a minute ventilation sensor as the threshold adjustment sensor. In this embodiment, the minute ventilation sensor determines the sleep threshold value, and the patient’s activity level is compared to the value to

² Sazonov, page 1296.

detect sleep onset and termination. The patient's heart rate is also monitored to confirm that the patient is asleep when sleep onset is detected. A specific combination of values of activity level, minute ventilation, and heart rate indicate that the patient is in fact asleep (i.e., an activity level below a threshold value determined by the minute ventilation value in combination with a sleep-compatible heart rate).

The activity level, minute ventilation, and heart rate are not mathematically combined to determine an overall sleep metric value that indicates an overall probability of the patient being asleep. The minute ventilation is used to adjust the sleep threshold. The patient's activity is compared to the threshold value to make a binary determination of whether the patient is asleep. If it is determined that the patient is asleep based on the comparison, a second binary determination of whether the heart rate is compatible with sleep is determined. If both binary determinations indicate sleep, sleep onset is confirmed. If the heart rate is incompatible with sleep, minute ventilation and patient activity continue to be monitored. The two determinations of sleep state are not mathematically combined to determine an overall probability of the patient being asleep. Instead, they are compared to provide a binary determination of whether the patient is asleep. Hatlestad does not even discuss determining an overall probability of the patient being asleep and, instead, describes making a binary determination that the patient is asleep.

Furthermore, the Examiner cited paragraphs [0135]-[0162] of Hatlestad as teaching determining a value of each of a plurality of sleep metrics, each of the plurality of sleep metric values determined based on a respective one of the physiological parameters. However, the cited portion of Hatlestad describes a variety of sleep quality metrics, which are completely unrelated to the sleep detection process described in Hatlestad's paragraphs [0090]-[0103]. Applicant's claims require that the plurality of sleep metric values that each indicate the probability of the patient being asleep based on the respective one of the plurality physiological parameters are mathematically combined to determine an overall sleep metric value that indicates an overall probability of the patient being asleep. The Hatlestad sleep detection process, which the Examiner characterized as a process of determining the overall sleep metric value, is completely unrelated to the sleep quality metrics described by Hatlestad, which the Examiner characterized as the plurality of sleep metric values. The Hatlestad sleep detection method does not use any of the sleep quality metric values to detect sleep onset and termination, much less mathematically

combine a plurality of sleep quality metric values. For at least these reasons, the Examiner's characterization of Hatlestad is incorrect.

Applicant's claims further require that the plurality of sleep quality metric values each indicate a probability of the patient being asleep. The Examiner acknowledged that Hatlestad does not disclose or suggest how the sleep metric values indicate a probability of the patient being asleep. Applicant submits that it is clear that the sleep quality metrics described in Hatlestad do not indicate a probability of the patient being asleep. As one example, Hatlestad teaches that undisturbed respiration sleep time may be calculated by subtracting sleep time in disturbed breathing from the total time asleep. The total time asleep may be determined using the binary sleep detection of Hatlestad discussed above. Hatlestad also describes disordered breathing detection methods that are used to determine sleep time in disturbed breathing.

Neither the undisturbed respiration sleep time, nor the sleep time in disturbed breathing, indicate a probability of the patient being asleep. In fact, none of the sleep quality metrics described in paragraphs [0135]-[0162] indicates a probability of the patient being asleep. As previously discussed, Hatlestad describes a sleep detection unit that determines whether the patient is asleep. The sleep quality metrics described in paragraphs [0135]-[0162] quantify the quality of the patient's sleep, and do not indicate a probability of the patient being asleep.

Neither Hatlestad nor Sazonov disclose or suggest determining a plurality of sleep quality metrics that each indicate a probability of the patient being asleep based on a respective physiological parameter. Additionally, neither Hatlestad nor Sazonov disclose or suggest mathematically combining a plurality of sleep metric values that each indicate a probability of the patient being asleep to determine an overall sleep metric value that indicates an overall probability of the patient being asleep. Sazonov describes determining a single probability value based on a signal from a single accelerometer sensor and making a binary determination of "Sleep" or "Wake" based on the single probability. Hatlestad does not disclose or suggest any sleep metric that indicates the probability of a patient being asleep and also fails to disclose or suggest mathematically combining any sleep metrics used in the sleep detection process.

For at least these reasons, the Examiner has failed to establish a *prima facie* case for non-patentability of Applicant's independent claims 53, 72 and 73 under 35 U.S.C. 103(a). Each of

claims 20-23, 26-33, 35-38, 40, 43-45, 55 and 57-62 depends upon one of independent claims 53, 72 and 33 and is also in condition for allowance. Withdrawal of this rejection is requested.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Office Action's interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

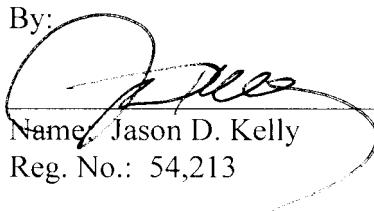
Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

1-5-09

SHUMAKER & SIEFFERT, P.A.
1625 Radio Drive, Suite 300
Woodbury, Minnesota 55125
Telephone: 651.286.8350
Facsimile: 651.735.1102

By:



Name: Jason D. Kelly
Reg. No.: 54,213